'Should bury data'

Kumar expressed his disappointment with the Ranbaxy management and, referring to the October 14 meeting, said that he had presented a plan to resolve the SAR issues.

When contacted by The Indian Express, Khanna said: "The statement supposedly attributed to me by Dr Brian Tempest is completely denied. I always stood for complete and unfailing compliance with all regulatory requirements and emphasised that Ranbaxy should maintain an impeccable and zero tolerance record in such matters. In my Chairman's messages which can be seen from published Annual Reports of the Company, there were unequivocal exhortations to maintain highest standards of quality assurance and regulatory compliance".

Tempest did not reply to an emailed query from The Indian Express.

The tribunal fined Malvinder Singh and his brother Shivinder Singh Rs 3,500 crore for defrauding Daiichi Sankyo by "deliberately" withholding information about the SAR and its significance from the Japanese pharma company. Daiichi had purchased a majority stake in Ranbaxy from the Singh brothers and for Rs 19,804 crore on November, 2008.

The tribunal noted that SAR, which was forwarded to the US Food and Drug Administration by Kumar's principal assistant Dinesh Thakur in 2005, was the basis of investigations by USFDA and the US Department of Justice. It culminated with Ranbaxy, under Daiichi, paying $500 m to the DOJ in 2013.

Internal emails exchanged between Tsutomu Une, Ranbaxy Board chairman and Daiichi Sankyo's points person in India, and Daiichi's consultant Dick Van Duyne also reinforce the tribunal's indictment.

On November 19, 2009, according to the tribunal, well over a year after Daiichi acquired Ranbaxy, Une commented that the DOJ had a "smoking gun" (a reference to the SAR) that could have, according to his diary entry for that day, created a "high possibility of a criminal penalty".

In due course, this and Une's other diary entries had a central role in the indictment.

Une's email to Daiichi's consultant Duyne noted that "the bad thing is the involvement of top management in the current compliance issues are identified". He also recorded that he had come to know that Ranbaxy "management wanted the evidence destroyed".

Van Duyne wanted to know who was this "top" management. Une replied: "The in-house email communications before 2006 has been provided by the whisperer...and DOJ found out that R's (Ranbaxy's) auditor as well as outside auditor cautioned to the Board members the issues which are exactly the same reasons as those relevant to the AIP (Application Integrity Policy)."

The FDA had invoked AIP which effectively suspended all new or pending applications or supplemental applications for drug approval against Ranbaxy on February, 2009.

Une added: "Furthermore, Dr Tempest and MS (an apparent reference to Malvinder Singh) ordered to break all the documents relating to the issues.This is the reason why the cases could be criminal even (though) no patients was (sic) harmed by the products. Also this is why FDA insists the issues caused by the corporate culture."

RHC Holding, where Malvinder and Shivinder Singh are the promoters, was asked specifically by The Indian Express about this statement of Une talking about Malvinder Singh asking to "break (discarding) the documents." The company replied: "The matter is sub judice and we cannot offer any comment in view of the confidentiality requirements." Une, who is still with Daiichi Sankyo, did not respond to queries from *The Indian Express*.

Ranbaxy's own

On Ranbaxy, he told the tribunal: "One of the observations in the warning letter (which the USFDA sent to Ranbaxy during the course of its investigations into the company) is that Ranbaxy did not have adequate resources, equipment and persons, to generate the stability data (for the drugs) they were reporting to FDA. Well, how are they reporting stability data to FDA if they didn't have the resources to generate them? Where is that stability data coming from?"

Answering his own question, he said: "That's not an ordinary cGMP (Current Good Manufacturing Practice) violation. They are discarding data. They have a standard operating procedure that authorises the discarding of data. That is shocking. That is not an ordinary cGMP violation. That is terrible, that is beyond the pale."

The cGMP regulations for drugs and biological products essentially refer to minimum requirements that must be met for the methods, facilities, and controls used in manufacturing, processing, and packaging.

Citing an example, Cooper said in his deposition: "They (Ranbaxy) have two refrigerators at 4 degrees Centigrade, packed with 1,300 samples. They are at 4 degrees but they are labelled for 25 degrees, 30 degrees, or 40 degrees Centigrade. That is gross, shocking. That is not routine, that is not ordinary cGMP stuff, and it put patients at risk."

In his 2005 letter, Kumar, in a reference to the corporate culture at Ranbaxy, said, "this practice (of data falsification) had been going on for a number of years, with the explicit instructions from management, those who aided this were rewarded and others did for fear of themselves and their jobs." Kumar was with Ranbaxy for less than four months.

Among other damning evidence, one of Ranbaxy's own external lawyers, W Warren Hamel of Baltimore-based Venable Partners, a law firm that was hired to deal with the DOJ investigations, told the tribunal that Kumar's SAR "paints a picture of a company with an outlaw culture — a culture of doing what is necessary to get a drug approved and to market rather than doing what is right...from the low ranks to the then managing director and board of directors — was to obtain the drug approvals as quickly as possible, and that the legal requirements were no barrier; where data was available, Ranbaxy made it up; where Good Manufacturing Practice would have slowed it down, Ranbaxy disregarded it."

Hamel added that the SAR "was an enormous evidence of wrongdoing."

It was this culture that was again pointed out by a Ranbaxy's former employee, Suman Kathuria. Kathuria had written a letter to Malvinder Singh following the FDA warning letter of June 15, 2006, which was issued for Ranbaxy's Paonta Sahib facility.

The tribunal said Kathuria "spoke of some of the issues of data integrity and falsification, describing some of his 'haunting memories' of the goings on in Ranbaxy." In this letter, Kathuria explained how "computerised HPLC systems data integrity was continuously manipulated by filling a form outside quality system for corrections by the System Administrator".

High-performance liquid chromatography is an experimental, analytical tool used in the pharmaceutical industry to test products and detect the raw ingredient used to make them.

Kathuria also referred to how "batches of Cephalexin not meeting colour and clarity criteria and with foreign matter contamination were released..", and an "expert in fabricating false records...I saw the results recorded the bio burden tests and environmental monitoring in the morning using material that he had prepared the previous evening." Cephalexin is a bacterial infection medicine.